



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,383	03/30/2004	Robert A. Davey	D6484	5461

7590

06/23/2006

Benjamin Aaron Adler
ADLER & ASSOCIATES
8011 Candle Lane
Houston, TX 77071

EXAMINER

CHEN, STACY BROWN

ART UNIT	PAPER NUMBER
----------	--------------

1648

DATE MAILED: 06/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/813,383	Applicant(s) DAVEY ET AL.	
	Examiner Stacy B. Chen	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1648

DETAILED ACTION

This application has been transferred to Examiner Stacy Chen of Art Unit 1648. Please direct all future correspondence accordingly. Applicant's amendment and response filed April 11, 2006 is acknowledged and entered. Claims 36-40 are pending and under consideration.

Double Patenting

The provisional rejection of claim 36 of this application in view of claims 1, 8 and 9 of Application No. 11/036,568 is maintained for reasons of record. Applicant notes that a terminal disclaimer will be filed to obviate this provisional rejection.

Claims Summary and Interpretation

The claims are drawn to a method of screening for a compound that inhibits the virus binding and entry into target cells by generating viruses with wild-type envelope proteins and hybrid viral envelope proteins with an enzyme fused to the C-terminal end, infecting target cells with the recombinant particles in the presence and absence of a candidate compound and measuring activities of the enzyme in infected cells. Decreased enzyme activity indicates viral inhibition by the candidate compound. Specifically, the enzyme is luciferase. The envelope-enzyme fusion protein comprises envelope protein of murine leukemia virus. The wild-type viral envelope protein is from a virus selected from the group consisting of murine leukemia virus, HIV, retrovirus, vesicular stomatitis virus, arenaviruses, hanta virus, ebola virus and Venezuelan equine encephalitis virus. Also claimed is the measurement of enzyme activities in a 96-well plate.

Art Unit: 1648

Applicant asserts that the new limitation “such that the enzyme in the envelope-enzyme fusion protein is incorporated into the virus particles”, means that the reporter enzyme is incorporated into the virus particles that were generated by transfection of cells with the wild type envelope protein, the fusion protein and the plasmids encoding virus structural proteins. The new limitation encompasses incorporation of the enzyme into the *surface* of the virus particle.

Claim Rejections - 35 USC § 103

The rejection of claims 36 and 39 under 35 U.S.C. 103(a) as being unpatentable over Dulbecco (US 4,593,002) or Young et al. (US 5,916,563), in further view of Blumenthal et al. (Journal of Biological Chemistry; 1987; 262 (28): 13614-13619), is maintained for reasons of record.

The rejection of claims 36, 38 and 39 under 35 U.S.C. 103(a) as being unpatentable over Russel et al. (WO 94/06920) and Blumenthal et al. *supra*, is maintained for reasons of record.

The rejection of claims 37 and 40 under 35 U.S.C. 103(a) as being unpatentable over Dulbecco or Young et al., either in view of Blumenthal et al. as applied to claims 36 and 39 above, or Russel et al. and Blumenthal as applied to claims 36, 38 and 39 above, and further in view of Goldsmith et al. (US 6,451,598 B1), is maintained for reasons of record.

Response to Arguments

Applicant's arguments have been carefully considered but fail to persuade. Applicant's substantive arguments are primarily directed to the following:

Art Unit: 1648

- Applicant asserts that the new claim limitation, “such that the enzyme in the envelope-enzyme fusion protein is incorporated into the virus particles”, renders the claims unobvious over the cited references. Applicant explains that in the instant invention, the reporter enzyme is incorporated into the virus particles that were generated by transfection of cells with the wild type envelope protein, the fusion protein and the plasmids encoding virus structural proteins. Applicant argues that entry of the virus particle into the cells results in breaching of the membrane and release of the enzyme. Applicant asserts that the cited references, particularly Blumenthal et al., describe fluorescent labeling of the virus on the external surface as opposed to the instant invention’s encapsulation of the enzyme into the viral particle.
- In response to Applicant’s argument, the Office agrees that the enzyme label described in Blumenthal et al. is on the external surface of the virus. The Office also notes that claims do not recite a limitation regarding encapsulation of the enzyme label. The claims recite, “incorporated into the virus particles”. The construct of Blumenthal et al. meets this limitation because the enzyme label is incorporated into the surface of the virus particle. Applicant appears to be reading a meaning into the limitation that is not represented by the claim language. Applicant refers to encapsulation and the method by which the virus particles are made (expressing the enzyme internally), however, the claims do not reflect this concept.
- Applicant also argues that since the virus taught by the cited prior art references is labeled externally with the enzyme, there is a greater possibility for the enzyme to be

Art Unit: 1648

exposed to its substrates before entry of the virus or action of entry inhibitors.

Applicant argues that such a virus will provide information about virus binding, but not its entry mechanism or the action of entry inhibitors.

- In response to Applicant's argument, the instantly claimed method does not recite limitation regarding the degree of sensitivity or efficiency. The methods do not recite steps of elucidation of entry mechanisms or elucidation of inhibitory mechanisms of the candidate compounds (beyond a general inhibition activity). The cited reference provide motivation to arrive at the claimed invention and a *reasonable* expectation of success. Therefore, the rejection is maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1648

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Stacy B. Chen 6/20/06

Stacy B. Chen
Primary Examiner
June 20, 2006